

### **REMARKS/ARGUMENTS**

Claims 39-48, 52-59, 65-69, 76-80 are presently pending in the application.

#### **Drawing Objection**

Regarding the objection to the drawings under 37 C.F.R. 1.83(a) at the top of page 2 of the Office Action, Applicants note that this objection was imposed in the Office Action dated September 13, 2005, responsive to which Applicants submitted a replacement drawing page showing an imager adapted to provide an image of a user and further showing an infrared imaging device. The December 20, 2006 Office Action appeared to accept the substance of the replacement drawing page but required that elements in the drawing be labeled with indicia denoting or connoting their function, responsive to which Applicants submitted another replacement drawing page with the requested indicia. The following Office Actions of July 13, 2007 and April 1, 2008 apparently accepted the other replacement drawing sheet, as it was not objected to or critiqued.

The Advisory Action now states that the drawing objection is maintained due to the Applicants' "apparent reliance ... on the particular visualization capabilities...e.g. in claim 74...which are not clearly illustrated." However, since **claim 74 does not pertain to an imager, and is cancelled**, withdrawal of this rejection is appropriate.

#### **Domestic Priority Information:**

The outstanding Office Action states, on page 3, that "applicants have deliberately chosen to remove the reference to provisional application 60/064,465 from the specification..." but this removal from the first paragraph of the specification was submitted only after the Examiner had objected to Applicants' first paragraph in about three or four consecutive Office Actions without providing what Applicants regard, with all due respect, to be a clear reason for the objections. For example, the Office Action's repeated language that "the presumption and assertion that the priority of 60/064,465 is inherent" is considered unclear to Applicants. The perhaps non-optimal wording accounts for why almost every one of Applicants' responses to the objection did something different. If Applicants' phone calls would have been returned or if Applicants would have received a more responsive or

situation-tailored explanation on what in the first paragraph of the specification was objectionable, the various actions and deletion, aimed at pleasing the examiner, would not have occurred. With this Amendment, Applicants retract that deletion and reintroduce the prior language that U.S. Application No. 09/188,072 claims the benefit of, and incorporates by reference the contents of, U.S. Provisional Application No. 60/064,465.

The Advisory Action states that “the attempt to include the provisional application 60/064,465 ... for the very first time ... is improper ... and ... is clearly greater than the 16 month period.” Applicants refer the Examiner to the application data sheet (cf. Exhibit A), which was filed within a month of the filing of the current application. As set forth in the Patent Rules, the application data sheet is considered to be a part of the nonprovisional application for which it has been submitted. (See 37 CFR 1.76.) The same section of the Patent Rules further states that providing domestic priority information by way of an application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and § 1.78(a)(2) or § 1.78(a)(5), and that domestic priority information submitted this way **need not otherwise be made part of the specification**.

Official Notice:

Regarding the statement at the bottom of page 3 of the Office Action that “these determinations ... are now considered prior art,” Applicants disagree and submit that, as far as Applicants are concerned, such is not the case. Applicants have not admitted any of the mentioned determinations to be or as containing prior art. The Office Action asserts that a traversal by Applicants of a determination must be seasonably made and must be adequate the failure of either of which justifies the Examiner to state that the determination is “taken” to be admitted prior art. However, the Examiner’s taking, or interpreting, his prior determination to be admitted prior art does not make that determination non-traversable. Thus, Applicants respectfully traverse the Examiner’s determinations, even to the extent they have already been taken, and Applicants iterate clearly for the record that these determinations made by the Examiner are challenged, and not admitted by the Applicants to be prior art.

The Advisory Action takes official notice of “the obviousness” of configuring devices for and using devices for the removal of fat tissues in joints or the abdomen,

since these are known sites of fat tissue. Applicants submit that official notice may be taken as to **issues of fact but not legal issues or conclusions, such as “the obviousness,”** and, thus, traverse the Examiner’s official notice. Furthermore, while configuring and using devices for removal of fat in the abdomen may be known, such knowledge does **not provide equivalency to removal of fat in joints** regardless of whether or not both regions may contain fat.

The Applicants’ representative is sincerely appreciative of Examiner Shay’s comments as set forth in the Advisory Action, and kindly request, further, that, for the above determinations, the Examiner provide a combinable reference that would be considered by one skilled in the art at the time of the invention to teach and to provide motivation for such determinations, to meet the currently claimed invention, for a clear record and for betterment of Applicants understanding thereof for traversal. To the extent such knowledge is common or widely known, the effort required to corroborate such knowledge with a reference, for the record, may be minimal.

No Prima Facie Case of Obviousness:

Claims 39-46, 48, 52, 53, 65-68, 76, 77, 79 and 80 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Rizoiu et al. (International Publication No. WO97/07928) in combination with Paolini et al. (U.S. Patent No. 6,206,873), Massengill (U.S. Patent No. 6,106,516), and allegedly “admitted prior art of ... removal of fat ... sterile fluids ... plastics ... and ... steel”; and claims 47, 54-59, 69 and 78 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Rizoiu et al. in combination with Paolini et al., Massengill, and allegedly “admitted prior art of ... removal of fat ... sterile fluids ... plastics ... and ... steel” as applied to claims 39-46, 48, 52, 53, 65-68, 76, 77, 79 and 80 and further in view of Kittrell et al. (U.S. Patent No. 4,913,142). These rejections are respectfully traversed.

The below highlighting, in bold, is provided to facilitate the Examiner’s rapid review, rather than to be argumentative .

Applicants’ independent claims contain combinations of characteristics connoting architectures and arrangements adapted for **tunneling through cartilage and, especially, hard tissue** (e.g., bone).

To the extent recitations of such uses are not specifically included in the claims, they need not be, **as structures rather than uses** are claimed. These defined

structures are not anticipated and would not have been obvious even without such inclusion.

Consistent with the recited **structures** (designed to achieve these uses), the inventive cannulas do not need to possess a leading tip that is shaped to pierce, cut, or disrupt the tissue, and, instead, according to a preferred implementation, the laser and fluid can do at least part, and, in typical applications, substantially all, of the cutting, with the **structure** of the cannula distal end being constructed to emit such items (the laser and fluid) to effectuate tunneling of the device through cartilage and hard tissue.

Figures 9b and 11b of the current application contain images of preferred blunt-tip **structures** of Applicants' invention for laser-cutting, e.g., connective tissue.

According to the claimed **structure**, suitable for such hard or semi-hard tissue procedures, the positioning of Applicants' interaction zone off-axis to the central (longitudinal) axis of the cannula, when combined with rotation of the cannula about the axis during the tunneling, can, while not claimed as a process, allow for generation of a "tunnel" sufficiently sized in width to allow the cannula to be advanced/navigated therethrough/therein to an operable, or even optimal, degree.

The Paolini disclosure, on the other hand, is not concerned with (a) laser-cutting, or (b) tunneling through cartilage or bone, since its disclosure is limited to lipolysis applications. With reference to lines 14 and 15 of Paoline, the lipolysis is described as being performed subcutaneously rather than under cartilage or bone, for aesthetic treatments. Line 24 of column 2 of Paoline classifies its lipolysis procedures as accomplishing liposuction.

The Office Action states that Paolini can be used "for removal of fat tissue in joints" but Applicants do not agree and, furthermore, do not see where the Examiner has obtained support for such assertion. Applicants request that the Examiner kindly provide a combinable reference that would be considered by one skilled in the art at the time of the invention to teach and to provide motivation for such a use to meet the currently claimed invention.

The Paolini disclosure specifically teaches away from laser-cutting connective tissue by iterating that its laser is **for lipolysis** (see column 3, lines 31-34, 49-53 and 61-67; column 4, lines 4-6, 8-10, 16-22, 26-29, etc.). Paolini appears to distinguish its invention from prior art devices on the precise point of it not cutting or damaging collagen.

The Paolini laser does not intend to and indeed apparently **cannot cut collagen** (see column 1, lines 60-63 “maintains collagen... substantially unaltered or undamaged”; column 2, lines 18-21 “the most important aspect...is the fact that the collagen fibers remain intact...very important”; column 2, lines 18-21 “collagen fibers ... are not damaged...and remain intact”; lines 3, lines 34-37 “intensity and wavelength of the laser...maintains collagen...substantially unaltered....”). It does not seem coincidental that the Paolini laser settings are not suitable, e.g., too low, to effectuate such cutting.

Paolini contains no teaching, suggestion, or even hint, of its laser performing piercing of or tunneling through cartilage or bone, which contexts are among those highlighting the advantageous off-axis feature of the currently claimed invention.

An interpretation that “Paolini et al envision the laser doing the...cutting,” such as occurring on page 4 of the Office Action, is misplaced and more likely than not impermissibly based on hindsight. The Office Action characterized Paolini’s claim 4 recitation, of “said piercing” being performed with a needle, as broadening the Paolini disclosure to piercings being performed with a laser. However, as explained above, **Paolini’s laser is limited to settings that cannot cut skin.** The recitation in the Paolini et al. claim 4 of a “sharp edge” does not broaden claim 1 to piercing with “lasers,” since the piercing of claim 1 could be performed, instead of with the sharp edge of a needle, with, for example: a blade-like member (column 3, line 29 “beveled end” not necessarily “sharp”); a scalpel; a non-laser/non-needle laparoscopic tissue-entry device, a non-laser/non-needle liposuction tissue-entry device; or the “point” rather than sharpened edge of a needle (column 3, line 31, 41 and 54 “point”; column 4, line 16 “pierce”). Thus, the mere fact that the claim 1 “piercing” term may be performed by something other than a “sharp edge” does not mean that claim 1 **discloses or teaches piercing by a laser.** It is noted that blade-like members, scalpels, non-laser/non-needle laparoscopic tissue-entry devices, non-laser/non-needle liposuction tissue-entry devices; and needle “points” are not specifically excluded from disrupting the collagen (such as collagen of skin) of the patient, but that the Paolini laser is.

Criticality:

The Examiner's requirement for some type of showing (e.g., of criticality) in connection with the presently claimed structure, is improper, especially in view of the content already of record concerning this issue. The Advisory Action seems to assert that, since Applicants have not disclosed/stated/argued that an off-axis structure is critical, it is obvious. Applicants interpret this position as an indication that the Examiner has not adequately set forth **reasons**, from the prior art of record, and **evidence** in support of modifying/combining the prior art to arrive at the currently claimed combinations.

As for the issue of when a showing of criticality is required by Applicant, it would appear that most "criticality" issues arise in the context of:

(a) overlapping ranges of values: The current discussion does not relate to ranges of values.

(b) features disclosed by Applicants as equivalent: No equivalency discussions appear in the record of the current filing or prosecution. Applicants, further, refer the Examiner to MPEP 2144.06 which indicates that equivalency must be recognized by the prior art, for the same purpose, and cannot be based on Applicants' disclosure.

(c) examiner has presented a prima facie case. MPEP sections regarding "criticality" seem to require evidence of "criticality" **only when** the Examiner has presented a prima facie case. As set forth above, no such case has been established. Certainly, an assertion that "it is not critical, therefore it is obvious" would not a prima facie case make. (Concluding that something is obvious, based on Applicants' disclosure, of course would amount to impermissible hindsight.)

In any event, regardless of the arrangement of the current facts with regard to the above (a), (b) and (c) conditions, a showing of criticality would not appear to be required in the current situation since, for example, the claimed features clearly have separate utility over the structures described in the prior art.

As for the issue of whether the **reason** for Applicants' claimed off-axis structure was disclosed in the as-filed application or mentioned early-on in the prosecution, there does not appear to be any requirement for such elucidation in the relevant authorities and examination guidelines.

The Advisory Action seems to interpret Applicants' position as seeking "use" protection by way of the presentation of the current apparatus claims. This interpretation is incorrect.

Applicants presently claimed structure includes, among other things, an interaction zone positioned off-axis to the central (longitudinal) axis of the cannula. While not submitting criticalities, Applicants point to the following **advantages**:

- (i) The inventive cannulas do not need to possess a leading tip that is shaped to pierce, cut, or disrupt the tissue, and, instead, according to a preferred implementation, the laser and fluid can do at least part, and, in typical applications, substantially all, of the cutting,
- (ii) Applicants determined, and, accordingly, designed, the architecture of the currently-claimed device to have an interaction zone positioned off-axis to the central axis of the cannula so that during tunneling through, for example, cartilage or hard tissue such as bone the cannula can be rotated about its axis to generate a "tunnel" sufficiently sized (e.g., enlarged) in width to allow the cannula to be advanced, or to be more easily advanced, therethrough, or to be navigated, or more easily navigated, during or after the tunneling process.

As presently presented, the independent claims in this application recite, for example, "the transmitter axis being (a) non-identical to, (b) non-overlapping with and (c) closer to the inner wall surface than the cannula axis" (claim 54), "the transmitter axis being disposed closer to the inner wall surface than to the cannula axis" (claim 65), and "a transmitter axis positioned closer to the inner wall surface than the cannula axis" (claim 66).

It is respectfully submitted that the current independent claims are neither anticipated by nor obvious in view of the prior art of record, and thus are allowable over the prior art of record. It is submitted that each of the presently pending dependent claims is allowable at least because of its dependency upon an independent claim, and further because of the additional limitations recited therein.

Reconsideration and withdrawal of the rejections under 35 U.S.C. 103(a) is respectfully requested. Applicants submit that the application is now in condition for allowance, and an early indication of same is requested.

Should the Examiner believe that a telephone conference with Applicants' representative would be helpful to advance the prosecution of the application, or for any other reason, he or she is kindly invited to contact the undersigned with any questions.

The Commissioner is hereby authorized to charge any needed fees to deposit account 50-1600.

Respectfully submitted,



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